



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the General Counsel

Office of the Chief Counsel  
Food and Drug Administration  
5600 Fishers Lane, GCF-1  
Rockville, MD 20857

May 3, 2004

Dockets Management Branch (HFA-305)  
Food and Drug Administration, Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

Re: In re Korangy Radiology Associates, P.A., et al.  
FDA Docket No. 2003H-0432

Dear Sir or Madam:

Enclosed for filing in the above-captioned matter is the original and one copy of Complainant's Motion For Leave To File A Reply Brief To Memorandum In Support Of Opposition Of Respondents To Complainant's Motion For Partial Summary Judgment.

If you have any questions, please call me at (301) 827-7138. Thank you.

Sincerely yours,

Douglas A. Terry  
Assistant Chief Counsel  
for Enforcement

Enclosure

cc w/enc.:

Hon. Daniel J. Davidson, A.L.J.  
Henry E. Schwartz

2003H-0432

NO 8

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UNITED STATES OF AMERICA  
BEFORE THE FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of )

KORANGY RADIOLOGY ASSOCIATES, P.A., )  
trading as BALTIMORE IMAGING CENTERS, )  
a corporation, )

and )

AMILE A. KORANGY, M.D., )  
an individual. )

ADMINISTRATIVE COMPLAINT  
FOR CIVIL MONEY PENALTY

FDA Docket: 2003H-0432

COMPLAINANT'S MOTION FOR LEAVE TO FILE A REPLY BRIEF TO  
MEMORANDUM IN SUPPORT OF OPPOSITION OF RESPONDENTS TO  
COMPLAINANT'S MOTION FOR PARTIAL SUMMARY JUDGMENT

Complainant, the Center for Devices and Radiological Health, Food and Drug Administration, United States Department of Health and Human Services, moves for leave to file a Reply Brief to the Memorandum In Support Of Opposition Of Respondents To Complainant's Motion For Partial Summary Judgment (Respondents' Memorandum), which was filed on April 30, 2004. Complainant filed Complainant's Motion for Partial Summary Judgment (Summary Judgment Motion) on April 2, 2004. In the Summary Judgment Motion, Complainant argues that each Respondent is liable for 193 violations of the Mammography Quality Standards Act of 1992 (MQSA), 42 U.S.C. § 263b. In Respondents' Memorandum, Respondents raise several legal issues, including the issue of whether Respondents may be held liable for the alleged MQSA violations pursuant to 42 U.S.C. § 263b(h) (3) (D).

Pursuant to 21 C.F.R. § 17.17(a), the Presiding Officer may

call for the submission of briefs to resolve a party's motion for summary decision on any issue. Complainant seeks the opportunity to respond to the issues raised in Respondents' Memorandum. Accordingly, Complainant requests that it be permitted to file a Reply Brief in response to the issues raised in Respondents' Memorandum. A proposed order granting this motion for leave to file a Reply Brief is attached hereto.

DATED: May 3, 2004.

Respectfully submitted,




Douglas A. Terry  
Attorney for Complainant  
Center for Devices and Radiological Health  
5600 Fishers Lane (GCF-1)  
Rockville, MD 20857  
Telephone: (301) 827-7138

**CERTIFICATE OF SERVICE**

I hereby certify that, on this third day of May, 2004, I have caused a copy of the foregoing Complainant's Motion For Leave To File A Reply Brief To Memorandum In Support Of Opposition Of Respondents To Complainant's Motion For Partial Summary Judgment and proposed order to be served by Federal Express overnight delivery, on:

Henry E. Schwartz  
Henry E. Schwartz LLC  
Attorney for Respondents  
901 Dulaney Valley Road, Suite 400  
Towson, MD 21204

  
\_\_\_\_\_  
DOUGLAS A. TERRY  
Attorney for Complainant  
5600 Fishers Lane (GCF-1)  
Rockville, MD 20857

UNITED STATES OF AMERICA  
BEFORE THE FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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FDA Docket: 2003H-0432

ORDER

By motion received in this office on May 3, 2004,  
Complainant, the Center for Devices and Radiological Health, Food  
and Drug Administration, United States Department of Health and  
Human Services, requested that it be granted leave to file a  
Reply Brief to respond to issues raised in the Memorandum In  
Support Of Opposition Of Respondents To Complainant's Motion For  
Partial Summary Judgment (Respondents' Memorandum), which was  
filed on April 30, 2004.

Pursuant to 21 C.F.R. § 17.17(a), the Presiding Officer may  
call for the submission of briefs to resolve a party's motion for  
summary decision. It appearing that full briefing on the issues  
raised in Respondents' Memorandum would materially assist the  
Presiding Officer in resolving Complainant's Motion For Partial  
Summary Judgment, which was filed on April 2, 2004,

It is ORDERED, that the motion is hereby granted and that  
Complainant shall file a Reply Brief to Respondents' Memorandum

within fourteen days of the date of this Order.

Dated this \_\_\_\_\_ day of May, 2004.

Daniel J. Davidson  
Administrative Law Judge  
U.S. Food and Drug Administration  
Room 9-57, HF-3  
5600 Fishers Lane  
Rockville, MD 20857